

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Epshtein et al.

Application No.: 10/522,653

Examiner: Szperka, M.

Filed: January 22, 2005

Group Art Unit: 1644

For: MEDICINAL AGENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER 37 CFR 1.132

I, O. I. Epshtein, Dr. Sc, do hereby declare as follows:

1. My name is Dr. Oleg I. Epstein (aka Epshtein). I am a widely recognized scientist in the fields of pharmacology and physiology. I authored over 100 articles in the peer-reviewed journals.

2. The company I lead, Materia Medica Holding, successfully sells the product covered by the above-identified application 10/522,653. I am the inventor of the '653 application.

3. I reviewed all references cited by the Examiner in the final Office Action mailed on April 2, 2008, namely, *Sinha*, *Davenas*, and *Feldman*. I am familiar with the *Epshtein* article cited by the Examiner.

4. It is my understanding that the Examiner argued that one skilled in the art would have a reasonable expectation of success that homeopathic dilution of PSA antibodies will work for treatment of prostate conditions based on the information in the cited references. In particular, it is my understanding that it is the Examiner's position once the effect of any homeopathic dilution of antibodies is known, one skilled in the art would expect that such treatment will work for any other antibodies.

5. Contrary to reasoning of the Examiner, it is my opinion that one skilled in the art would not expect the homeopathic technology to be able to achieve treatment objectives without significant experimentation. Quite simply, it is my opinion, as one well skilled in the art, that the information available in the art at the time the '653 application was filed was not sufficient to create an expectation asserted by the Examiner.

All statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment; or both, under Section 1001 of Title 18 of the U.S. Code and that such willful false statements may jeopardize the validity of any patent application issuing thereon.

Dated: August 29, 2008

A handwritten signature in black ink, consisting of a stylized, cursive letter 'L' followed by a horizontal line.